UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

December 14, 2005

MEMORANDUM

SUBJECT: Consent Agreement and Proposed Final Order to Resolve DuPont's Alleged Failure to Submit Substantial Risk Information Under the Toxic Substances Control Act (TSCA) and Failure to Submit Data Requested Under the Resource Conservation and Recovery Act (RCRA)

FROM: Granta Y. Nakayama
Assistant Administrator

TO: Environmental Appeals Board

The Office of Enforcement and Compliance Assurance requests that the Environmental Appeals Board (Board) approve the accompanying Consent Agreement and proposed Final Order executed by E.I. du Pont de Nemours and Company (DuPont) and the Environmental Protection Agency (EPA) that settles this matter for $10.25 million in penalties plus an additional $6.25 million expenditure for Supplemental Environmental Projects (SEPs).[1] This memorandum conforms to the Board's Consent Order Review Procedures dated January 5, 1993.

The Consent Agreement resolves violations of the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601 et seq., and the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. §§ 6901 et seq., as alleged in two administrative complaints filed on July 8, 2004 (subsequently amended on October 13, 2004), and December 6, 2004, copies of which are included with this transmittal package as attachments A and B.[2] The Consent Agreement also

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[1]The term "EPA" is used throughout this memorandum to refer to EPA's Enforcement program, other programs or the agency as a whole. The Environmental Appeals Board holds the delegated authority to issue the Final Order in this matter.

[2] By Order of Administrative Law Judge Barbara Gunning dated December 7, 2004, the two administrative actions were consolidated. See attachment C. The allegations in the first Complaint are discussed in this memorandum as Counts 1, 2 and 3. The allegation in the

simultaneously commences and concludes four additional alleged violations of TSCA, as discussed below. All eight alleged violations are collectively referred to in this memorandum as EPA's Action.

The Consent Agreement complies with Section 22.18(b) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Rules of Practice), 40 C.F.R. § 22.18(b). I have reviewed the Consent Agreement and determined that it is consistent with the statutes authorizing the Agency's action and that the civil penalty is appropriate.

I. Background

A. TSCA Substantial Risk Reporting Requirement

TSCA § 8(e), 15 U.S.C. § 2607(e), provides that a chemical manufacturer, processor, or distributor who obtains information which reasonably supports the conclusion that a substance or mixture presents a substantial risk of injury to human health or the environment shall immediately inform the Administrator. The requirement to inform the Administrator continues until either the person submits the information or has actual knowledge that the Administrator has been adequately informed through another source. EPA relies upon TSCA § 8(e) information to be made aware of potential risks to human health and the environment posed by chemicals. Congress established the TSCA § 8(e) reporting requirement to ensure that EPA would be informed about potential risks so that it could be able to take any appropriate action to protect the public or the environment. Failure to receive TSCA § 8(e) substantial risk information deprives EPA of being fully apprised of potential risks about chemicals and impairs EPA's ability to take those actions necessary to address potential risks to human health or the environment.

B. The Chemical at Issue

EPA's enforcement action against DuPont involves the synthetic chemical Amonium Perfluorooctanoate (APFO), also known as C-8 and sometimes called PFOA (Perfluorooctanoic Acid) because APFO disassociates to PFOA in water. PFOA is a perfluorinated detergent/surfactant which has been used by DuPont since 1951 in connection with Teflon®-related products at its Washington Works facility outside Parkersburg, West Virginia. PFOA is produced synthetically and formed through the degradation or metabolism of other fluorochemical products, such as fluorinated telomers that are used in non-stick coatings on carpets, clothing, and food wrappers.

December 6, 2004 Complaint is discussed in this memorandum as Count 4. There are four additional allegations raised and resolved in the Consent Agreement that are discussed in this memorandum as Counts 5, 6, 7 and 8.

C. Importance of Timely TSCA § 8(e) Reporting for PFOA

EPA has placed a high priority on understanding the impacts of PFOA. EPA has determined that PFOA is biopersistent in certain animals and associated with developmental effects in animals. As noted in the "Draft Risk Assessment of the Potential Human Health Effects Associated with Exposure to Perfluorooctanoic Acid and Its Salts," U.S. EPA, Office of Pollution Prevention and Toxics, Risk Assessment Division at 6; 11 (Jan. 4, 2005) (http://www.epa.gov/opptintr/pfoa/pfoarisk.htm), PFOA is considered to be bioaccumulative in humans with a long half-life of about 4.37 years and has the potential for developmental/reproductive toxicity and immunotoxicity in humans. The average human serum background level of PFOA in the general population of the U.S. is estimated to be approximately 5 parts per billion (ppb) and EPA expects this to be true worldwide. PFOA is not naturally occurring, thus all PFOA in human blood is attributable to human activity. EPA is seeking to identify the pathway or pathways (air, water, food, etc.) that result in human exposure to PFOA.[3]

D. EPA's Receipt of TSCA § 8(e) Information Regarding PFOA

On March 6, 2001, Robert A. Bilott, Esq., of Taft, Stettinius & Hollister LLP, sent copies of documents to EPA that he had obtained as part of class action litigation against DuPont. The class action had been looking into claims of PFOA drinking water contamination in West Virginia and Ohio around the DuPont facility. Bilott's documents indicated that DuPont had studied PFOA in pregnant workers and their offspring as early as May, 1981 and thus had obtained the first direct human evidence of PFOA crossing the placenta in humans. Bilott's documents also indicated that DuPont had performed substantial sampling of drinking water in the homes and businesses near its facility, and that DuPont understood in 1987, and confirmed repeatedly in 1988 and 1991, that the drinking water in the homes near its Washington Works facility in West Virginia exceeded DuPont's community exposure guideline for PFOA exposure.

On September 15, 2004, Bilott sent EPA the results of blood sampling not submitted by DuPont that showed elevated levels of PFOA in the blood of twelve people in the community near DuPont's Washington Works facility. The samples showed levels of PFOA ranging from 15.7 ppb to 128 ppb.

On December 20, 2004, DuPont provided EPA with blood sampling results for persons that were not employed at the facility that had been performed sometime in 2002. These ten individuals lived in the vicinity of DuPont's Washington Works Plant in West Virginia and reportedly drank water from private wells located near one or more DuPont landfills at which DuPont disposed PFOA.

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[3]On January 12, 2005, EPA submitted a Draft Risk Assessment for PFOA to the Science Advisory Board for peer review.

While the parties were in negotiations to resolve Counts 1-4 (discussed in detail below), DuPont advised EPA that it had additional materials that it intended to submit to EPA, without conceding that the information was subject to the requirements of § 8(e). In December 2004 and January 2005, DuPont submitted forty-one boxes of information related to PFOA to EPA. EPA reviewed these documents to see if any of the information had not been submitted to EPA as required by TSCA § 8(e). Most of the information had been submitted previously to the Agency. Of the information that had not been previously submitted, EPA determined that three studies should have been submitted under TSCA. This information included two toxicity studies performed on July 11, 1997. One was an inhalation study that exposed male rats to an aerosol form of a perfluorinated chemical. The other was also an inhalation study and involved a different perfluorinated chemical sprayed on rats. DuPont has claimed the identity of these chemicals as Confidential Business Information (CBI). A third study involved an August 29, 1997 inhalation study on rats of a third perfluorinated chemical the identity of which has also been claimed as CBI.

E. Background of the RCRA Claim

The DuPont Washington Works facility operates under a permit pursuant to Section 3005(a) of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6925(a), and 40 C.F.R. Part 270. In 1989, EPA issued the portion of DuPont's hazardous waste permit ("Permit") that addresses the provisions of the Hazardous and Solid Waste Amendments of 1984. Pub. L. 98-616, Title II, Nov. 8, 1984. The Permit included provisions implementing, inter alia, RCRA § 3004(u), 42 U.S.C. § 6924(u), and 40 C.F.R. § 264.101. Section 3004(u) of RCRA and 40 C.F.R. § 264.101 require "corrective action for all releases of hazardous waste or constituents from any solid waste management unit at a treatment, storage, or disposal facility seeking a permit under [Subchapter C], regardless of the time at which waste was placed in such unit." RCRA § 3004(u); 40 C.F.R. § 264.101.

Under Part I, § I.7 of DuPont's Permit, EPA may request any relevant information to determine whether cause exists to modify the Permit, revoke and reissue the Permit, terminate the Permit, or to determine compliance with the Permit. On May 5, 1997, EPA requested that DuPont provide "known toxicological information" about PFOA in EPA's conditional approval of DuPont's Verification Investigation Report, a report required under the terms of the permit used to describe whether there has been a release of a hazardous waste from a solid waste management unit. On June 6, 1997, DuPont responded to EPA's request for known toxicological information about PFOA but did not include the human blood sampling information concerning the transplacental movement of PFOA that DuPont obtained in 1981. Upon a review of the records associated with DuPont's permit in early 2004, EPA confirmed that DuPont had failed to submit the 1981 data to EPA pursuant to the terms of the RCRA permit.

II. Summary of the Violations

Count 1 alleges that DuPont failed to comply with TSCA § 8(e) when it failed to submit to EPA the information from 1981 that demonstrated transplacental movement of PFOA in humans. This data was substantial risk information concerning PFOA.

Count 2 alleges that DuPont failed to comply with TSCA § 8(e) when it failed to submit to EPA the information concerning PFOA contamination of the drinking water inside people's homes. This data was substantial risk information concerning PFOA.

Count 3 alleges that DuPont violated RCRA § 3005(a) when DuPont failed to comply with the EPA request for "known toxicological information" by failing to submit the 1981 toxicity data concerning PFOA.

Count 4 alleges that DuPont failed to comply with TSCA § 8(e) when it failed to submit the information from 2004 concerning the elevated PFOA blood levels in twelve individuals living in the vicinity of the Washington Works facility. This data was substantial risk information concerning PFOA.

Count 5 alleges that DuPont failed to comply with TSCA § 8(e) when it failed to report data concerning blood test results of ten individuals living near the Washington Works facility with elevated levels of PFOA. This data was substantial risk information concerning PFOA.

Counts 6, 7 and 8 allege that DuPont failed to comply with TSCA § 8(e) on three occasions when it failed to report toxicity data about the three different rat inhalation studies performed on July 11, 1997 and August 29, 1997. Each of the three studies was substantial risk information concerning the aerosol form of a perfluorinated chemical.

III. Penalty Policy

EPA uses its Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA §§ 8, 12 and 13 (March 31, 1999) (TSCA Penalty Policy) and the RCRA Civil Penalty Policy (June 23, 2003) to help interpret penalty factors contained in each statute and to be consistent in penalty assessment for similarly situated violators committing similar violations. The policies are not binding and are used on a case-by-case basis. TSCA § 16(a)(2)(B) requires EPA to take into account the statutory factors of "Nature," "Circumstances," "Extent," and "Gravity." RCRA § 3008 requires EPA to consider the seriousness of the violation and the violator's good faith efforts to comply. EPA also considers the violator's ability to pay, effect on ability to continue to do business, economic benefit, history of violations and other matters as justice may require.

The TSCA Penalty Policy addresses the potential seriousness of the failure to report under TSCA § 8(e) by providing for, under the proper circumstances, penalty assessments for each day of violation. The TSCA Penalty Policy provides that the full statutory maximum penalty for each day of violation may be appropriate if the new information that was not reported would have had a bearing on the Agency's risk assessment and chemical control efforts. EPA considers human exposure data to be more important than animal data. EPA also considers whether the failure to report directly interfered with the Agency's ability to address potentially unreasonable risks to human health. The TSCA Penalty Policy reflects the seriousness EPA attaches to violations of TSCA § 8(e) by not placing caps on the penalties assessed for these violations. Accordingly, for a violation that EPA determines to have directly disrupted EPA's ability to address situations involving potentially imminent hazards, unreasonable risks, or substantial endangerment to health or the environment, the TSCA Penalty Policy provides that the penalty will be the statutory per day maximum authorized under TSCA for the full period of noncompliance. For those violations of TSCA § 8(e) where the failure to report would not have directly interfered with the Agency's ability to address imminent hazards, unreasonable risks, or substantial endangerment, the Penalty Policy generally provides for penalties based on each month of violation (the statutory maximum for each day of violation divided by 30).

IV. The Settlement

EPA settled this case in two phases. The first phase resolved the first four Counts that had been alleged in the two complaints. The second phase resolved Counts five through eight that arose from information DuPont provided to EPA after the two complaints were filed.

A. Phase 1: The First Four Counts

Count 1 involves information that DuPont obtained in 1981 regarding human data demonstrating the rate of movement of PFOA from a mother to her fetus. EPA was not aware of this information until Bilott sent it to EPA in 2001. EPA considers the data to be highly significant because the Agency did not previously have any data from humans showing movement of PFOA from mother to fetus, only data from lab animals. The TSCA Penalty Policy notes that violations involving TSCA § 8(e) information that directly disrupt EPA's ability to address situations involving potentially unreasonable risk or substantial endangerment to human health should be assessed the maximum penalty for each day of the violation. The policy further notes that "failure to comply with the TSCA § 8(e) reporting requirements can be the most serious violations of TSCA § 8. These reports alert the Agency to new information which may have a bearing on the Agency's chemical hazard/risk assessment and chemical control efforts."

For a violation such as Count I, the Penalty Policy provides for the statutory maximum penalty on a per-day basis. The statutory maximum for nearly twenty years of daily penalties for

Count 1 is $183,837,500.[4] EPA believed that DuPont's failure to provide the information regarding the transfer of PFOA across the placenta was significant human data and should be assessed under the circumstances factor of the statute with the highest penalty because of its potential harm to EPA's ability to assess risk to human health. However, after calculating the theoretical maximum penalty, the Agency had to assess other factors in determining the appropriate penalty, particularly the risk that the theoretical maximum could not be obtained in litigation (i.e., the "litigation risk").

There were several potential litigation risks that could have prevented EPA from obtaining the theoretical maximum. The first is whether the Administrative Law Judge (ALJ) would have found it appropriate to assess a penalty at the higher rate as information that "directly disrupts" the Agency's risk management activities under TSCA. DuPont was prepared to argue that the information was not of such great significance. DuPont has asserted that it had submitted similar data in lab animals and that the data from 1981 was merely confirmatory and not conclusive of substantial risk. Moreover, DuPont would have noted that EPA has never obtained an ALJ assessment of a penalty under TSCA § 8(e) for per day assessment of the statutory maximum penalty. EPA believes it would have prevailed on this issue, but there is no certainty in litigation. If the ALJ determined that EPA did not prove that the failure to submit the information "directly disrupted" EPA's risk assessment then, under the Penalty Policy, the maximum penalty would be divided by 30 to $6,127,917 for Count 1.

Second, the theoretical maximum assumes that EPA would succeed in obtaining penalties for each day between DuPont obtaining the information in 1981 and EPA receiving the information in 2001. However, there is case law on the statute of limitations that could significantly reduce the penalty that EPA could obtain. DuPont could have asserted that the five year statute of limitations for civil penalties, 28 U.S.C. § 2462, would prevent EPA from bringing Counts 1, 2, or 3, at all, as the action was filed more than five years after DuPont originally failed to submit the information. EPA would have responded that DuPont's failure to submit the information constituted a continuing violation for each day the information remained unsubmitted. The Board's decisions support EPA's argument here and EPA believes it would have prevailed. (See, e.g., In re Lazarus Inc., 7 E.A.D. 318 (EAB 1997) and Newell Recycling, 8 E.A.D. 598 (EAB 1999)) Yet, even if EPA had prevailed on the continuing violations issue, DuPont could have further argued that the penalties should be limited to those violations which occurred within five years prior to the date of the Complaint. If DuPont prevailed on such a

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[4] This value assumes a penalty starting on June 15, 1981, the date the information became available to DuPont, and continuing until March 6, 2001, the date EPA learned of the information. The calculation involves two statutory maximum penalties because of the inflation adjustment rule. One portion of Count 1 would be for the time period prior to January 30, 1997 and includes 5,709 days at $25,000 which equals $142,725,000. For the days after January 31, 1997, the higher daily penalty of $27,500 for 1,495 days totals $ 41,112,500. Adding these two amounts together results in a hypothetical statutory maximum of $183,837,500 for Count 1.

theory for limiting penalties, the statutory maximum for Count 1 would have been $16,582,500.[5]

EPA also faced significant litigation risk that could have prevented any recovery of penalties under Count 2. Count 2 involved the contamination of drinking water in people's homes well above the internal standard of 1ppb that DuPont had set as part of its community exposure guidelines for PFOA in water. There is evidence that DuPont became aware of levels of PFOA exceeding 1 ppb coming out of the tap in homes in the 1980's but did not report those data to EPA as required under TSCA § 8(e). Prosecution of this Count carried a litigation risk, however, because EPA took a series of administrative actions contemporaneous with DuPont's testing that may have altered the reporting obligations under TSCA. Starting in February of 1991, the Agency announced its desire to bring the chemical industrial sector into better compliance with TSCA § 8(e), and offered companies the chance to participate in the TSCA § 8(e) Compliance Audit Program, or CAP, and to settle past instances of noncompliance. While the program was designed to be a backward-looking audit of past unreported data, the series of Agency statements by which EPA announced and developed the CAP[6] seem to have left some ambiguity regarding the reporting requirements in place during the time the CAP was being developed and eventually executed with DuPont, between February 1991 and June 27, 1996.

Judge Gunning recognized this litigation risk at the hearing on the motions for summary judgment on Count 2, noting in her Order Denying Motions for Accelerated Decision on Counts II and III, "quite frankly, I am having great difficulty making sense of the Revised Addendum with the four corners of the Consent Agreement, the CAP Agreement, and the Revised Addendum." She indicated that she was unable to discern a clear meaning of the enforcement waiver that DuPont claimed had been given to all environmental contamination reporting under TSCA § 8(e) as part of EPA's CAP. This language from the Judge raises the possibility that EPA would have recovered no penalty for Count 2 because EPA waived its enforcement authority as part of the settlement under the CAP. Even if the Judge were to have found EPA had not waived its statutory authority to take an action, there were questions about fair notice issues that may have prevented a penalty against DuPont under TSCA for its environmental contamination.

Therefore, as part of defending Count 2, EPA has agreed that it would limit the penalties for failure to provide data related to the drinking water contamination to the time period prior to the 1996 settlement under the CAP. The penalties for Count 2 would only be calculated from 1992 until 1996. The TSCA Penalty Policy assigns daily penalties where the alleged violations do not directly disrupt the EPA's ability to address substantial risk by using the statutory

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[5]Using the time period of July 8, 1999 (five years before the filing date of July 7, 2004) and March 6, 2001 (the date EPA received the data) multiplied by $27,500.

[6]These communications included Federal Register notices, letters to and agreements with individual participating companies, "enforcement waivers" granted during the audit period, as well as various amendments and addenda issued over the span of five years.

maximum amount and dividing by thirty. Thus, the unmitigated (gravity) penalty under the TSCA Penalty Policy for Count 2 is $1,036,433. As with Count 1, EPA would have asserted that collection of penalties is not prevented by the statute of limitations under a continuing violation theory. If, as with Count 1, DuPont prevailed on limiting collection of penalties for continuing violations to those which occurred within five years of the complaint, EPA would have recovered no penalties for Count 2.

Count 3 is a RCRA violation and, under that Penalty Policy, the gravity-based penalty could be $312,300. This gravity-based penalty is derived by treating the "potential for harm" as moderate and the "extent of deviation" as moderate, resulting in a penalty of $8,000 (which is within the range of $5,500 to $8,799). EPA selected the moderate category for the "potential for harm" axis of the matrix because the toxicological information that EPA requested would be used, inter alia, to develop a risk-based comparison level for PFOA to be used in the Health Assessment that DuPont was performing as part of corrective action at the facility. Because there was no health-based criteria available for PFOA, DuPont was required to propose to EPA a provisional risk-based comparison level based, conservatively, on toxicity data. Without having all toxicological information about PFOA, EPA could not completely assess whether the risk-based comparison level that DuPont proposed was appropriate. EPA also recognizes that the RCRA Penalty Policy expressly identifies failure to respond to a formal information request, the violation at issue in Count 3, may have serious implications and merit substantial penalties where the violation undermines the statutory or regulatory purposes or procedures implementing the RCRA program. EPA selected the moderate category for the "extent of deviation" axis of the matrix because while DuPont did provide some toxicological information, and therefore partially responded to the information request, it withheld rare and important human health data -- data that fits squarely within the category of requested information, i.e., "toxicological information."

Under the penalty policy, it is presumed that multi-day penalties are appropriate for days 2-180 of violations with a moderate-moderate gravity-based designation. Because this violation could be designated as moderate-moderate in the gravity-based penalty matrix, and because the violation continued from June 11, 1997 to at least March 7, 2001, the date that EPA received the transplacental movement information, it is appropriate to treat this violation as a multi-day violation. Accordingly, the multi-day penalty component, under the multi-day matrix, would be a per day penalty of $1700 (which is within the range of $1,760 to $275) for 179 days. To calculate the $312,300 penalty, the multi-day penalty component, $304,300 would be added to the $8,000. As with Count 1, EPA would have asserted that collection of penalties is not prevented by the statute of limitations under a continuing violation theory.

Count 4 is another TSCA violation, but it is only a few days long in duration and it is not of the nature that directly disrupted EPA's ability to address an unreasonable risk situation. Thus the unmitigated (gravity) penalty under the policy is $42,250.[7] [8]

All four Counts were considered in settlement collectively since they all pertained to the Counts in the filed complaints. These first four Counts were settled in principle for a penalty of $10 million plus an additional $5 million to be spent on SEPs.

B. Phase 2: The Last Four Counts

DuPont provided information concerning PFOA blood levels in individuals who did not work at the Washington Works facility that gave rise to the violation in Count 5. EPA's review of the boxes of documents submitted by DuPont after the complaints had been filed resulted in three additional alleged violations of TSCA § 8(e) in Counts 6, 7 and 8.

Since all four of the additional alleged violations involved TSCA § 8(e) violations for PFOA or other perfluorinated chemicals, they were collectively settled with the initial four violations. The failure to provide the blood level data on the residents involved less than three months of failure to report. EPA considered this violation to be a major violation for which per day penalties applied, but did not directly disrupt EPA's ability to address situations involving unreasonable risk or substantial endangerment, and thus the Penalty Policy would assess one day at the statutory maximum and the remaining days would each have a penalty of the statutory maximum divided thirty. The proposed penalty for the three alleged violations for failure to report the three aerosol applications of the perfluorinated chemicals likewise would have been

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[7] $\$32,500 + \frac{(10 \text{ days} - 1) \times \$32,500}{30} = \$42,250$

This equation uses September 5, 2004 until September 14, 2004 for dates of penalty.

[8] EPA determined that no additional penalty was necessary to recover the economic benefit of the violations contained in Counts 1-4 because, under the existing methods for determining economic benefit for reporting obligations under TSCA § 8(e) or RCRA corrective action permits, the economic benefit was much less than the penalty collected. EPA also decided that DuPont is such a large company that the ability to pay and the ability to continue to do business were not a problem for this company. Lastly, EPA noted that DuPont has prior violations under TSCA.

divided by thirty under the Penalty Policy. These violations were resolved for an additional $250,000 penalty and $1.25 million in SEPs.[9]

These three violations again posed significant statute of limitations risk since DuPont obtained the information in 1997. It was possible that EPA would not have been able to recover any penalty had DuPont prevailed on that issue. There were also additional issues involving the clarity of the guidance with respect to inhalation exposure. These issues would have been issues of first impression.

C. Appropriateness of the Penalty as a Whole

EPA believes that the penalty it received for the eight counts in this action is appropriate under the statutory penalty factors of TSCA and RCRA. Since the theoretical maximum penalty for Count 1 is so much larger than for the other seven counts, EPA's determination as to the appropriate penalty for the case was based largely on its evaluation of the seriousness of the violation and the other factors, particularly litigation risk, associated with Count 1. There was significant risk under Count 1 that EPA would not be able to prove successfully 1) that the violation directly disrupted EPA's risk assessment activities under TSCA, and 2) that the violation was of a continuing nature and therefore not partly or totally barred by the statute of limitations. Thus, the Judge could have been weighing these issues in deciding whether it would be appropriate to assess nearly twenty years of penalties. EPA took all of these risks into consideration when determining an acceptable penalty for settlement. EPA faced similar litigation risks associated with the statute of limitations for Counts 2, 3, and 6-8. EPA also faced the risk of no recovery under Count 2 due to the lack of clarity surrounding the effect of the 1991 TSCA Compliance Audit Program. In light of the substantial litigation risk, EPA determined that a variance from the TSCA and RCRA penalty policies would be appropriate in this matter. EPA also considered the deterrent effect that a $10,250,000 penalty plus $6,250,000 expenditure for SEPs would have on the regulated TSCA community generally and DuPont in particular.

The $10.25 million penalty is the largest administrative penalty under any statute ever obtained by EPA. It is also more than ten times greater than the largest TSCA § 8(e) penalty EPA has ever obtained.[10] Therefore, although the penalty is a significant reduction from the theoretical maximum penalty under the statute and the TSCA and RCRA penalty policies, EPA

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[9]Counts 6, 7 and 8 dealt with information obtained by DuPont in 1997 and submitted to the Agency in December 2004. The aggregate unadjusted gravity based penalty for these violations is approximately $4.5 million.

[10]It is worth noting that the highest TSCA § 8(e) settlements prior to this action were the $1,000,000 payments several companies made as part of the TSCA § 8(e) Compliance Audit Program.

believes it will have a significant deterrent effect on the regulated community. In fact, since filing the initial complaint in July 2004, there has been a significant increase in TSCA § 8(e) and useful information sent into EPA by industry that does not rise to the level of substantial risk under TSCA § 8(e), but has been submitted to EPA as "For Your Information" (FYI).[11]

This settlement also establishes a commitment by DuPont to spend $6.25 million to perform two voluntary SEPs. The first SEP is a Fluorotelomer-based Product Biodegradration SEP (Biodegradation SEP). Pursuant to this SEP, DuPont will investigate the biodegradation potential of certain chemicals to breakdown to form PFOA. The SEP, valued at $5 million and to be completed in three years, will evaluate nine of DuPont's commercial fluorotelomer-based products in commerce prior to the settlement. Using two types of biodegradation studies, the SEP will help the public to better understand the inherent degradation potential of fluorotelomer-based products to form PFOA and the behavior of such products when released to the environment.[12] DuPont will use independent laboratories to perform all work associated with the Biodegradation SEP and will hire an independent third party to serve as a Panel Administrator for a Peer Consultation Panel. The Peer Consultation Panel will address specific charges related to the biodegradation studies. The public will have the opportunity to nominate Peer Consultation Panel members.

The scientific community, including EPA, does not have a full understanding of how people are exposed to PFOA. In 2003, EPA released a preliminary risk assessment for PFOA and started a public process, involving industry, stakeholders, and others, to identify and generate additional information to better understand the sources of PFOA and the pathways of human exposure. This Biodegradation SEP will help industry, scientists, the public, and EPA

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[11]FYI submissions often come from trade associations and industry consortia that submit TSCA § 8(e) notices on behalf of member companies covered under the reporting requirement. EPA has received FYI submissions covering a wide variety of chemical substances and mixtures from chemical companies, trade associations, unions, public interest groups, civic associations, private citizens, academic institutions, state and other federal agencies, as well as similar organizations/agencies in foreign countries. These notices contain information on human exposure, epidemiology, toxicity test results, monitoring studies, environmental fate, and other information that may be pertinent to risk assessment.

[12]OECD Guideline 303A, one of the two methodologies that will be followed for the biodegradation studies to be performed under the Biodegradation SEP, is subject to copyright. EPA has purchased a copy of OECD 303A and has included it in the CBI version of the settlement package. See CBI settlement package, Appendix A, Attachment C1. In the non-CBI version of this settlement package, EPA has not included a copy of OECD Guideline 303A but has prepared a document explaining where and how it can be purchased and where it can be viewed. See Attachment D to this memorandum. See also non-CBI settlement package, Appendix A, Attachment C1.

examine the potential sources of PFOA in the environment and potential routes of human exposure to PFOA. For instance, one of the biodegradation studies will help determine if commercial fluorotelomer-based polymer products breakdown to form PFOA, which could explain a source of PFOA in the environment. The other biodegradation study will examine the behavior of commercial fluorotelomer-based polymer products in a simulated waste water treatment plant, which could explain both a source of PFOA in the environment and a route of human exposure to PFOA. The results of these studies will assist EPA in determining a more accurate assessment of the potential risks posed by PFOA and by chemicals that may degrade to form PFOA, and to identify what voluntary or regulatory actions, if any, would be appropriate. In implementing the SEP, DuPont has agreed to require the laboratories it contracts with to follow the Agency's Good Laboratory Practices regulations as well as prepare and follow a Quality Assurance Project Plan.

The Second SEP is a Microscale Chemistry and Green Chemistry SEP in Junior High Schools and High Schools in Wood County, West Virginia. Pursuant to this SEP, DuPont will spend $1.25 million in five junior high schools and three high schools. The goals of this SEP include reducing the adverse impact to public health by minimizing the potential exposure to chemicals in schools, reducing the adverse impact to the environment in and around Wood County, West Virginia by minimizing hazardous waste generated at schools, and enhancing science safety in all of the schools involved in the SEP. The implementation of this SEP will involve close coordination with teachers and administrators in the participating schools. The SEP is expected to be completed over a three year period beginning on the date that the settlement is approved by the Board.

V. Human Health and Environmental Concerns

This administrative action involves information about the movement of PFOA from pregnant women to their babies, the contamination of public drinking water supplies in the vicinity of DuPont's Washington Works Facility, additional substantial risk information related to PFOA and a request for PFOA toxicity information as part of RCRA corrective action. The Agency regards this information as potentially useful in its ongoing priority review to understand the potential risks that PFOA may pose to human health or the environment. TSCA § 8(e) information is extremely important to alert the Agency to potential risks so that EPA may prioritize its assessment of chemicals so that the most hazardous chemicals are studied immediately.

VI. Past or Pending Actions

DuPont has three prior TSCA § 8 reporting violations. On October 3, 1996, a Consent Order was signed resolving TSCA § 8(e) violations as part of the CAP. On December 2, 1997, a Consent Order was signed resolving TSCA § 8(a) violations concerning Notices of Commencement of production of a new chemical. On September 29, 2003, a Consent Order was

Consent Order was signed resolving TSCA § 8(a) violations concerning Notices of Commencement of production of a new chemical. On September 29, 2003, a Consent Order was signed resolving TSCA § 8(a) violations concerning Inventory Update Rule violations.

VII. Conclusion

For the foregoing reasons, I recommend that the EAB approve the Consent Agreement and sign the Proposed Final Order.

Attachments

cc: Peter Robertson, DuPont Counsel